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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,947	08/03/2001	Michel Andre Crepeau	131542	8375

25944 7590 05/29/2007

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
05/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/921,947	CREPEAU, MICHEL ANDRE	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *164-219* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *164-219* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted March 19, 2007 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 164-219 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claims Kirk (USPN 4966779) in view of each of Parfitt (Martindale 32nd ed pp. 1358-1359, 1366-1370), Winstrom et al. (USPN 3708583), Tipton et al. (USPN 5,747,058), Ames et al. (USPN 3,639,587), and Alderman et al. (USPN 4,678,516), and in further view of Bergemann et al (USPN 6,096,699).

3. Kirk teaches water miscible emulsified formulations for use as nutritional additives to food products (col. 1, lines 7-13). The composition is taught to comprise 5-55% of a vitamin component, 3-30% of an oil component, 0.5-10% of a modified lecithin (nonionic emulsifier), 3.5-12% of sorbitan fatty acid ester (nonionic emulsifier), 5-30% water, and 0.5-10% propylene glycol (col. 1, lines 25-43; col. 4, lines 12-16). Vitamins A, D, E and K are taught as useful in the invention (col. 2, lines 10-14). Preservatives are optional components of the composition (col. 4, lines 23-27). Kirk does not specifically teach the combination of preferred preservatives, an alkyl lactate, the preferred vitamins or the preferred concentrations.

4. Parfitt teaches that Vitamin A is known in the art to consist of either retinol or its esters, including the propionate (p. 1358, col. 1). Parfitt also teaches that Vitamin E is known in the art to include dl-Alpha tocopheryl acetate (p. 1369, col. 1-2).

5. Winstrom et al. teaches a vitamin additive for addition to animal feeds (col. 1, lines 4-5). The additive is taught to comprise vitamins A, D2, D3, and E (col. 2, lines 5-8). Vitamin A compounds useful in the invention are selected from Vitamin A palmitate and Vitamin A acetate (Vitamin A precursors) (col. 3, lines 1-42). Winstrom et al. also teaches the use of antioxidants to prevent biological deterioration and degradation of the vitamins (col. 6, lines 5-7). Ethoxyquin is taught to be a preferred agent for protecting the vitamins from deterioration and degradation (col. 6, lines 8-26). Ethoxyquin is exemplified as comprising 1.5% of an additive composition (col. 8, lines 30-45). Other preservatives are also taught to be useful, e.g., BHT, BHA, sorbic acid (fungicide), etc. (col. 6, lines 26-31).

6. The Tipton et al. patent teaches high viscosity liquid compositions useful for the delivery of biologically active substances (See Column 1, lines 4-5; and Column 6, Lines 50-52). This composition can be administered by a variety of means, including topically, orally, or parenterally (See Column 10, Lines 39-49). Vitamins. such as vitamin E, are included among the possible biologically active substances useful for this composition (See Column 6, Lines 62-63; and Column 8, Line 1 5). Ingredients that may comprise this composition include oils and fats such as vegetable oil and corn oil (See Column 9, Lines 49-54); non-ionic surfactants, preferably polyoxyethylene sorbitan fatty acid esters (See Column 11, Lines 40-54); co-surfactants including ethyl alcohol, propylene glycol. and non-ionic surfactants such as polyethylene glycol (See Column 11, Line 60 to Column 12, Line 12). It is preferred that a solvent also be included

in the formulation, as a viscosity-decreasing agent. The presence of such a solvent allows for easier flow and easier formulation as an emulsion (Sec Column 5, Lines 50-57,. and Column 10s Lines 50-52). Suitable solvents include ethanol and ethyl lactate (See Column 10, Lines l 5-16), and wherein the amount of solvent may be in the range of 10-50% (claims 6-7). Ames et al. teaches that ethyl lactate is particularly useful in pharmaceutical compositions comprising vitamins A E and/or D, wherein the amount may be in the amount of 1-40%. See, particularly, col. 5, lines 10-18, and claim 1. Alderman et al. teaches that ethyl lactate and butyl lactate are similarly useful as pharmaceutical acceptable excipients. See, particularly, the abstract, and col. 5, lines 24-25. Bergemann et al. teach that C1-C4 alkyl lactate ester (10-90%) forms safe organic solvent with fatty ester with preferred flash point in excess of 212 ^{o}F. See, particularly, col. 3, line 27 to col. 4, line 5. Therefore, Tipton, Ames et al., Alderman et al. and Bergemann et al as whole reveal that lactate esters are well-known pharmaceutical or food acceptable excipients, particularly useful as solvent, viscosity modulator, etc. and provide safe feature as part of solvent.

7. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the specific vitamins are as herein claimed because (1) Kirk teaches the use of Vitamins A, D and E in general; (2) Winstrom et al. specifically teaches Vitamin Da as a vitamin D compound useful in feed additives; and (3) Parfitt teaches the vitamin compounds, instantly claimed as vitamin precursors, as known in the art to be useful as A and E vitamins. One would have been motivated to utilize the specific vitamins as instantly claimed because of an expectation of success in preparing a nutritional feed additive, as taught by Kirk.

8. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the vitamin compositions of Kirk or Winstrom et al. by incorporating alkyl lactate ester to the composition, either as part of the solvent, or as viscosity modulator because alkyl lactate esters are well-known pharmaceutical and food acceptable excipients and particularly as solvents or viscosity modulator, and further because alkyl lactate ester with fatty ester are known to form a safe solvent system.

9. It would have been obvious to one of ordinary skill in the art at the time of the invention to add the preservatives ethoxyquin and sorbic acid to the composition of Kirk because (1) Kirk and Winstrom are both directed to food additive compositions', (2) Kirk teaches the addition of preservatives, in general, to the composition', (3) Winstrom et al. teaches that ethoxyquin is a preferred agent for protecting the vitamins from deterioration and degradation', (4) Winstrom et al. teaches that sorbic acid is a preservative optionally added to the composition. One would have been motivated to add the preservatives of Winstrom et al. to the composition of Kirk et al. because of an expectation of success in preserving the composition in general, as taught by Kirk, and preparing a food additive composition wherein the vitamins are protected from deterioration and degradation, as taught by Winstrom et al.

10. It would have been obvious to one of ordinary skill in the art to prepare a composition with the concentrations as instantly claimed because the claimed concentrations overlap with those as taught by the combined references. It is well established that "where the general conditions of a claim are disclosed in the prior ad, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to the Arguments

Applicants' amendments and remarks submitted March 19, 2007 have been fully considered, but are not persuasive.

11. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching, suggestion and motivation are found in the prior art and in the knowledge generally available to one of ordinary skill in the art. Applicants argue that the compositions disclosed in each of the cited references are different each from the other with respects to the utility of the composition, the intended function of particular ingredients, etc. Applicants also argue that none of the cited references, or their combination, teach the particular composition herein claimed. The examiner recognizes that an obviousness determination is not a results of rigid analysis based on the express teaching of the cited references. The knowledge generally available to one of ordinary skill in the art (such as common sense of those skilled in the art) should be taken for consideration. "Under the correct analysis, any need or problem

known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." See, 82 USPQ2d 1385, 1397 KSR International Co. v. Teleflex Inc. (U.S. Supreme Court, 2007).

12. Considering the cited references as a whole, one of ordinary skill in the art would have recognized that alkyl lactate esters are well-known pharmaceutical and food acceptable excipients and particularly as solvents or viscosity modulator, and further because alkyl lactate ester with fatty ester are known to form a safe solvent system. Therefore, it would have been obvious to employ alkyl lactate ester as solvent or other excipients in a vitamin composition. One of ordinary skill in the art would have been motivated to make a vitamin composition as claimed for making a safe vitamin composition suitable for animal consumption.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. WANG

SHENGJUN WANG
PRIMARY EXAMINER

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Art Unit 1617